UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/176,664	10/21/98	SALKOFF L	018512-00012

020350 HM12/0410
TOWNSEND AND TOWNSEND AND CREW LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO CA 94111

EXAMINER	
BASI,N	
ART UNIT	**PAPER NUMBER**
1646	13

DATE MAILED: 04/10/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/176,664	Salkoff et al
Examiner	**Group Art Unit**
Nirmal. S. Basi	1646

☒ Responsive to communication(s) filed on *Jan 21, 2000*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-44* is/are pending in the application.

Of the above, claim(s) *17-25 and 28-44* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-16, 26, and 27* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-44* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *7*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. Response to Restriction requirement filed 1-21-00 has been entered, Preliminary Amendment filed 3/8/99 has been entered.

Corrected Filing Receipt

2. The processing of requests for corrected filing receipts delays the issue process and because such corrected filing receipts are not needed in order to have the correct information printed on the patent. A corrected filing receipt is not necessary for correct printing because the inventors' names, the title of the invention and any priority information are separately captured by the data capture contractor from documents within the application file wrapper and not from PALM data (which is used to generate the filing receipt. The inventors and the spelling of their names are taken from the originally filed executed oath or declaration or any later papers correcting the information thereon. The title of the invention is taken from the application papers and any amendments. Foreign priority information is also taken from the oath of declaration. In view of this and the fact that filing receipt are now generated earlier in the application process (see *Changes In Practice In Supplying Certified Copies And Filing Receipts*, 1199 O. G. 38) June 10, 1997), the PTO is changing its practice with respect to requests for corrected filing receipts. The new practice is that corrected filing receipts will **not** be mailed after the date of mailing of a Notice of Allowance and Issue Fee Due unless special circumstances exists which compel such action.

Election/Restriction

3. Applicant's election with traverse of Group II (Claims 1-16 and 26-27), in Paper No. 12 (1-21-00), is acknowledged. The traversal is on the ground(s) that the seven groups set forth by the examiner all stem from a common concept and theory, and thus related and as such, prosecution of the claims of Groups I-VII would not place a substantially greater burden on the examiner. This is not found persuasive because a search of groups I-VII would not be co-extensive particularly with regard to the literature search. Further, Groups I-VIII are distinct from each other for reasons of record as stated in paper number 11 (12-17-99). An examination of the materially different, patentably distinct inventions in a single application would constitute a serious undue burden on the examiner. Further the Applicants note that the nucleic acid products of Group II can be used in the screening methods of Group IV and the Restriction Requirement does not provide a materially different, alternative us for the products and methods. The nucleic acids of Inventions II and the methods of Inventions IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Invention may be used in hybridization assays.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejection, 35 U.S.C. 112, second paragraph

4. Claims 1-16 and 26-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 13 are indefinite because the method of determining the molecular weight has not been identified. A value for the molecular weight is entirely dependent upon the method by which it is determined and differs with different methods (e.g. denaturing gel, native gel, calculated from amino acid sequence, gel filtration etc.). Recitation of a molecular value without reference to the method by which it was measured is indefinite.

Claims 1, 17 and 26 are indefinite because the antibodies can not be generated against SEQ ID NO:s:1, 3, 16, or 18 because the sequences are mere characters on a page. It is suggested that the claim be amended to include language such as, generated against the polypeptide disclosed in SEQ ID NO:1 etc.

Claim 7 is indefinite because the nucleic acid cannot hybridize to SEQ ID NOs:4, 17 or 19 because the sequences are mere characters on a page. It is suggested that the claim be amended to include language such as, to the nucleic acid disclosed in SEQ ID NO:4 etc. Similarly claim 13 is indefinite because the nucleic acid cannot hybridize to SEQ ID NOS:2, 4, 17 or 19 because the sequences are mere characters on a page.

Claims 2 and 3 are indefinite because it is not clear what is a mSlo3 or hSlo3 encoded polypeptide. Since the names mSlo3 or hSlo3 are not an art accepted description of the proteins they

do not sufficiently describe said proteins. The names mSlo3 or hSlo3 do not provide any structural limitations so as to allow the metes and bounds of the claim to be determined. It is suggested mSlo3 or hSlo3 be identified by SEQ ID NO:.

Claims 6-7 and 13 are indefinite because "moderate stringency hybridization conditions" are not specified. The metes and bounds of the group of sequences that would meet the limitations of the claim depend upon the precise conditions under which hybridizations were performed including wash conditions. Since the hybridization and wash conditions dictate which DNA sequences remain specifically bound to the DNA of SEQ ID NO:2, 4, 17 and 19 the metes and bounds of the claims cannot be determined without the disclosure of said conditions.

Claims 10-11 are indefinite because "stringent hybridization conditions" are not specified. The metes and bounds of the group of sequences that would meet the limitations of the claim depend upon the precise conditions under which hybridizations were performed including wash conditions. Since the hybridization and wash conditions dictate which DNA sequences remain specifically bound to the DNA of SEQ ID NO:8-15 the metes and bounds of the claims cannot be determined without the disclosure of said conditions.

Claim 12 is indefinite because it not clear what is a "variant". "Variant" has not been defined in the claims nor specification so as to allow the metes and bounds of the claim to be determined. Further the claim is indefinite because the term "variant" carries no weight in terms of structure and function and encompasses numerous alterations and reads on unrelated nucleic acid molecules.

Claim 14 is indefinite because it not clear what is a "a core domain". "A core domain" has not been defined in the claims nor specification so as to allow the metes and bounds of the claim to be determined. Further amino acids 35-641 must be identified by SEQ ID NO:.

Claims 4-5, 9, 15-16 and 27 are indefinite for depending on a base claim or intermediate claim and fail to resolve the issues raised above.

Claim Rejection, 35 U.S.C. 112, first paragraph

5. Claims 6-7, 10-11, and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated DNA of SEQ ID NOS:2, 4, 17 and 19 encoding a polypeptide of SEQ ID NO:1, 3, 16 and 18 does not reasonably provide enablement for DNA hybridizing under unspecified stringent conditions. The, specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Stringent hybridization conditions have not been provided. Therefore the hybridization conditions recited in the claim do not constitute a meaningful structural limitation. Due to the large quantity of experimentation necessary to identify the polypeptides with the structural and functional features of instant invention without any disclosure of the hybridization or wash conditions, the unpredictability of isolating proteins unrelated to SEQ ID NO:s 1, 3, 16 and 18, undue experimentation would be required of the skilled artisan to make or use the claimed invention in its full scope.

6. Claim 12 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding at least 15 contiguous amino acids from a monomer having amino acid SEQ ID NO: 1, 3, 16 and 18 does not reasonably provide enablement for variants thereof. The, specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Although variants of the above mentioned monomers can be made said variant carries no weight in terms of structure and function and encompasses numerous alterations and reads on unrelated nucleic acid molecules. Due to the large quantity of experimentation necessary to identify the variant with the structural and functional features of instant invention, the unpredictability of the effects of mutation on the structure and function of proteins, and the breadth of the claim which fail to recite structural and functional limitations, undue experimentation would be required of the skilled artisan to make or use the claimed invention in its full scope. Further the applicant has not disclosed which variants would be expected to retain activity or how to use a commensurate number of said variants that are inactive.

7. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding a polypeptide monomer of a pH sensitive potassium channel having amino acid SEQ ID NO: 1, 3, 16 and 18 does not reasonably provide enablement for a monomer encoding a core domain that has greater the 60% amino acid sequence identity to amino acids 35-641 of a Slo3 core domain. The, specification does not enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claim encompasses mutants, variants and derivatives of the amino acid sequence of SEQ ID NOs: 1, 16 and 18. The claims read not only on naturally and non-naturally occurring proteins. Due to the large quantity of experimentation necessary to identify the mutant, variant and derivatives with the structural features of instant invention without disclosed functional features, the lack of direction/guidance presented in the specification regarding the identification, purification, isolation and characterization of said mutant, variant and derivatives, the unpredictability of the effects of mutation on the structure and function of proteins (since mutations are also encompassed by the claim), and the breadth of the claim which fail to recite functional limitations, undue experimentation would be required of the skilled artisan to make or use the claimed invention in its full scope. Further the specification does not teach how to construct active proteins and to use a commensurate number of said proteins which functionally inactive.

8. **Claim Rejections, 35 U.S.C. 102,**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12 is rejected under 35 U.S.C. 102(a) as being anticipated by Mccobb et al (IDS Ref. AP). Mccobb et al disclose an isolated nucleic acid encoding at least 15 contiguous amino acids from a pH sensitive channel polypeptide having an amino acid sequence of SEQ ID NO:1 with conservatively modified amino acids thereby meeting the limitations of claim 12.

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Thursday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-0294.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi
Art Unit 1646
April 4, 2000

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER